

REMARKS

A. Amendments to the Claims

In this paper, Applicants have amended claims 6 and 11 to specify that the antigen is a “capsular polysaccharide”. Support for this amendment is generally found throughout the originally filed specification [e.g., see ¶ [21], which states that “[a]s disclosed for the first time herein, Fragment C of tetanus toxin, often referred to as “TTc”, can be used as a carrier protein for polysaccharides, such as for capsular polysaccharide vaccines for protection against bacterial and fungal infections.” Additional minor stylistic amendments have been made to claims 1 and 6.

Applicants respectfully submit that no new matter has been added by these amendments.

B. Election/Restriction Requirement

In the Office Action issued on November 3, 2008, the Examiner contends that Applicants’ claims 1-15 do not relate to a single inventive concept under PCT Rule 13.1, because the claims allegedly lack the same or corresponding special technical features. Accordingly, the Examiner requires Applicants to elect one of the following three claim groups for prosecution:

Group 1: corresponding to claims 1-5, drawn to a method of increasing immunogenicity of a vaccine or an antigen by conjugating the antigen to a tetanus toxin fragment C.

Group 2: corresponding to claims 6-10, drawn to a method of immunizing a patient against infection.

Group 3: corresponding to claims 11-15, drawn to a conjugate vaccine.

In addition, the Examiner requires a species election, which depends on the elected group as follows:

- a) If electing Group 1 for prosecution, Applicants are required to make a species election as to the type of organism (i.e., bacterium or fungus as recited in claims 2 and 4, respectively) and to name the specific bacterium or fungus, as recited in claim 3 (if the elected organism is a bacterium) or claim 5 (if the elected organism is a fungus).
- b) If electing Group 2 for prosecution, Applicants are required to make a species election as to the type of organism (i.e., bacterium or fungus as recited in claims 7 and 9, respectively) and to name the specific bacterium or fungus, as recited in claim 8 (if the elected organism is a bacterium) or claim 10 (if the elected organism is a fungus).
- c) If electing Group 3 for prosecution, Applicants are required to make a species election as to the type of organism (i.e., bacterium or fungus as recited in claims 12 and 14, respectively) and to name the specific bacterium or fungus, as recited in claim 13 (if the elected organism is a bacterium) or claim 15 (if the elected organism is a fungus).

In response, Applicants provisionally elect Group 3 for prosecution, which is readable on claims 11-15. In addition, Applicants provisionally elect “bacterium” and “Streptococcus group B” as the species and subspecies, respectively, to be examined initially.

Applicants make these elections with traverse. Applicants' claims, as amended, do not lack unity of invention, because the amended claims are linked by a common special technical feature to form a single general inventive concept. The special technical feature in this case is an immunogenic conjugate comprising a carbohydrate (e.g., a capsular polysaccharide) covalently bonded to tetanus toxin Fragment C.

U.S. Patent 5,443,966 to Fairweather et al. ("Fairweather"), which is cited by the Office Action for allegedly destroying the unity of invention of Applicants' claims, does not teach or disclose the immunogenic conjugate that links Applicants' claims as a special technical feature. To the contrary, Fairweather is limited to compositions that contain unconjugated tetanus toxin Fragment C mixed with other ingredients. For instance, the passage of Fairweather cited by the Office Action (i.e., col. 3, lines 20-24) only refers to vaccines containing unconjugated tetanus toxin Fragment C and makes no mention of the claimed immunogenic conjugate molecule:

A vaccine for conferring immunity to tetanus comprises fragment C provided according to the invention and a pharmaceutically acceptable carrier or diluent. The vaccine may include other antigens to provide a multi-valent vaccine (Fairweather, col. 3, lines 20-24).

Notably, there is no disclosure in this passage (or any other passage) of Fairweather that the "other antigens" recited in passage above are covalently attached to tetanus toxin Fragment C. Accordingly, Fairweather does not disclose the claimed immunogenic conjugate molecule comprising tetanus toxin Fragment C covalently attached to a carbohydrate, such as a capsular polysaccharide.

In view of the foregoing, Applicants respectfully maintain that the claims do not lack unity of invention and respectfully request reconsideration and withdrawal of the election requirement.

AUTHORIZATION

The Commissioner is hereby authorized to charge any additional fees which may be required for consideration of this Amendment to Deposit Account No. 50-3732, Order No. 13564-105027.

In the event that an extension of time is required, or which may be required in addition to that requested in a petition for an extension of time, the Commissioner is requested to grant a petition for that extension of time which is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to Deposit Account No. 50-3732, Order No. 13564-105027.

Respectfully submitted,
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